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<p>(21) International Application Number: PCT/US99/23528</p> <p>(22) International Filing Date: 8 October 1999 (08.10.99)</p> <p>(30) Priority Data: 09/170,359 13 October 1998 (13.10.98) US</p> <p>(71) Applicant: EMBOL-X, INC. [US/US]; 645 Clyde Avenue, Mountain View, CA 94043-2213 (US).</p> <p>(72) Inventor: JANG, Yue-Teh; 43659 Skye Road, Fremont, CA 94539 (US).</p> <p>(74) Agent: KAPPOS, John, C.; Lyon & Lyon LLP, 633 West Fifth Street, Suite 4700, Los Angeles, CA 90071-2066 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: PERCUTANEOUS FILTRATION CATHETER FOR VALVE REPAIR SURGERY AND METHODS OF USE</p> <div data-bbox="276 1134 1347 1449"> </div> <p>(57) Abstract</p> <p>This invention is a percutaneous filtration catheter used to entrap emboli from a patient's aorta, and heart during cardiac surgery. The catheter has an elongate member (1), a proximal end (3), and a distal end (2). A balloon occludent (5) is mounted on the distal end of the elongate member, and an expandable filter (10) is mounted on the elongate member distal the balloon occludent. Methods for using the devices is also disclosed herein.</p>		

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DESCRIPTION

Percutaneous Filtration Catheter For Valve Repair Surgery And Methods Of Use

Field of the Invention

- 5 The present invention relates generally to filter devices for placement in a blood vessel to capture embolic material, and more particularly to a catheter system having an associated filter for percutaneous placement in an aorta to entrap embolic material from the aorta and heart during cardiac surgery.

Background of the Invention

- 10 Stroke has become a major source of morbidity following coronary artery bypass and other cardiovascular surgeries, including valvular repair, septal defect repair, removal of atrial myxoma, aneurysm repair, and myocardial drilling. Classic factors associated with an increased post-operative stroke rate are advanced age, severe left ventricular dysfunction, long standing diabetes, protracted cardiopulmonary bypass time, severe
15 perioperative hypotension, history of previous stroke, and bilateral carotid disease. Possible mechanisms of perioperative stroke include a reduction in cerebral blood flow through a stenotic extracranial or intracranial vessel, embolization of atherosclerotic debris from an ulcerated carotid artery plaque or aortic plaque, embolization of post-infarction left ventricular mural thrombus or atrial thrombus, and embolization of air inadequately
20 evacuated from the heart or aorta. In valvular repair surgery, manipulation of the heavily calcific aortic or mitral valve may result in calcium dislodgment in the left coronary artery or left ventricle, with subsequent embolization. Although atheromatous debris most frequently embolizes to the brain, other affected body sites include the spleen, kidney, pancreas, and gastrointestinal tract. Embolization of these peripheral organs can lead to
25 tissue ischemia or death.

- In addition to stroke, other factors, e.g., chest wall trauma, contributing to morbidity in cardiac surgeries often arise from the use of cardiopulmonary bypass for circulatory support and median sternotomy. Minimally invasive procedures using beating-heart and port-access approach have been developed to achieve aortic occlusion,
30 cardioplegia delivery, and left ventricular decompression to allow coronary revascularization and other cardiac procedures to be performed in a less invasive fashion.

A need therefore exists for less invasive devices and methods which facilitate aortic occlusion and/or cardioplegia delivery in cardiac surgeries and provide an arterial filter for reducing a patient's risk of perioperative stroke.

Summary of the Invention

5 The present invention provides a percutaneous filtration catheter having the ability to capture emboli, including atheromatous fragments, fat, myocardial tissue debris, and air. The catheter further includes capabilities to provide aortic occlusion and cardioplegia delivery in cardiac surgeries, especially in heart valve repair.

10 In one embodiment, the catheter comprises an elongate member having proximal and distal ends. The distal end has (1) a balloon occluder which communicates with a lumen carried by the elongate member, and (2) an expandable filter mounted on the elongate member distal to the balloon occluder. The balloon occluder and the expandable filter are operated independently at the proximal end of the elongate member. The expandable filter typically has a proximal edge bonded circumferentially and continuously
15 to the elongate member, and a distal edge which expands radially outward on activation.

 In another embodiment, the elongate member has a second lumen for infusing fluid, such as cardioplegia solution. The expandable filter may comprise an expansion frame, which may have an umbrella frame in one embodiment (for construction, see Barbut et al., U.S. Patent No. 5,769,816, and Ambrisco et al., U.S. Serial No. 09/070,660,
20 both incorporated herein by reference in their entirety) and an inflation seal in another embodiment (for construction, see Barbut et al., U.S. Patent No. 5,769,816). Furthermore, in certain embodiments, the expandable filter is operable by manipulating at least one pull string at the proximal end of the elongate member.

 The present invention also provides methods for capturing embolic material in
25 cardiac surgeries, thereby protecting a patient from neurologic complication due to embolization. The methods employ a percutaneous filtration catheter having an elongate member with proximal and distal ends, a balloon occluder mounted on the distal end of the elongate member, and an expandable filter mounted on the elongate member distal the balloon occluder. A percutaneous incision in a patient's peripheral artery, such as a
30 femoral or brachial artery, is made followed by insertion of the elongate member through the incision. In minimally invasive cardiac procedures, the percutaneous filtration catheter can be introduced percutaneously through a peripheral artery, or alternatively, through a minimal access port, often located in a patient's intercostal space, to the ascending aorta. The distal end of the catheter is then advanced into the ascending aorta. The filter is
35 expanded and positioned above the aortic valve to entrap embolic material from flowing

downstream to peripheral organs. The balloon occluder is inflated to provide circulatory isolation of the heart and coronary blood vessels from the peripheral vascular system. In the embodiment which includes a second lumen, the second lumen can be used to (1) deliver cardioplegia solution upstream to the heart to arrest cardiac function, or (2) to carry a pressure monitor. After cardiac arrest is achieved and cardiopulmonary bypass is initiated for circulatory support, a variety of cardiothoracic surgeries can then be performed, including coronary artery bypass grafting, heart valve repair, septal defect repair, removal of atrial myxoma, aneurysm repair, and myocardial drilling.

It will be understood that there are many advantages to using a percutaneous filtration catheter as disclosed herein. For example, the catheter provides (1) a percutaneous access for catheter insertion, obviating the need for an extensive tissue incision, (2) aortic occlusion through inflating a balloon occluder, thereby minimizing damage to the aortic wall and reducing the risk of emboli dislodgment as compared to traditional clamping, (3) a filter which entraps embolic material during cardiac surgery, thereby reducing a patient's risk of stroke perioperatively, (4) cardioplegia delivery upstream to the heart for cardiac arrest, and (5) access for devices to be introduced through an intercostal incision in minimally invasive cardiac procedures.

Brief Description of the Drawings

Fig. 1 depicts a percutaneous filtration catheter according to a first embodiment.

Fig. 2 depicts a percutaneous filtration catheter according to another embodiment, the catheter having a second lumen.

Fig. 3 depicts a percutaneous filtration catheter positioned in an ascending aorta.

Fig. 4 depicts different access routes for entry of the percutaneous filtration catheter for use in a patient.

Detailed Description

The devices and methods disclosed herein can be used in patients who have been identified as being at risk for embolization during cardiothoracic surgeries, thereby reducing their perioperative complications and length of hospital stay. Fig. 1 depicts a percutaneous filtration catheter according to one embodiment. The catheter has elongate member 1, distal end 2, and proximal end 3. Balloon occluder 5, which may comprise an elastomeric balloon, is mounted on elongate member 1 and communicates with inflation lumen 6. Expandable filter 10 is mounted on elongate member 1 distal the balloon occluder and can be operated by actuating mechanism 12 at the proximal end of the catheter.

Fig. 2 depicts another embodiment of a percutaneous filtration catheter having a second lumen. The catheter carries second lumen 20 in addition to lumen 6 which communicates with balloon occluder 5 and inflation port 7 for inflating the balloon occluder. Second lumen 20 communicates with port 22 and can be used to infuse cardioplegia solution, aspirate fluid or air, and/or to house a pressure monitor. Filter 10, mounted on elongate member 1, has expansion frame 15 and can be actuated by mechanism 12 at proximal end 3 of the catheter.

The length of a percutaneous filtration catheter is generally between 20 and 90 centimeters, preferably approximately 50 centimeters. The outer diameter of the catheter is generally between 0.1 and 0.4 centimeters, preferably approximately 0.2 centimeters. The balloon occluder, when inflated, will generally have a diameter between 1.0 and 5.0 centimeters, more preferably between 2.0 and 4.0 centimeters. The filter, when expanded, will generally have a diameter between 1.0 and 5.0 centimeters, more preferably between 2.0 and 4.0 centimeters. The foregoing ranges are set forth solely for the purpose of illustrating typical device dimensions. The actual dimensions of a device constructed according to the principles of the present invention may obviously vary outside of the listed ranges without departing from those basic principles.

Methods of using the devices disclosed herein are illustrated in Fig. 3. After a small percutaneous incision is made in a patient's femoral artery, distal end 2 of the percutaneous catheter is introduced through the incision and advanced into the ascending aorta. Expandable filter 10 is then expanded to entrap embolic material originating from the heart or the aorta, including air, atheromatous plaque, tissue debris, fat, or thrombi. Balloon occluder 5 is inflated through its communicating inflation lumen 6 to provide aortic occlusion for cardiopulmonary bypass. Cardiac arrest can be achieved by delivering cardioplegia solution upstream to the heart through lumen 20 and port 22. Lumen 20 and port 22 can also be used to place a pressure monitor or to aspirate fluid, blood, air, tissue, or plaque debris from the heart and the aorta. A surgeon then can proceed with various cardiothoracic surgeries.

Fig. 4 depicts different percutaneous entry sites for a percutaneous filtration catheter. The catheter is generally inserted through a patient's femoral arteries. Right groin 30 and left groin 32 are common percutaneous incision sites for introducing elongate member 1 of the catheter, shown here entering through left groin 32 in the left femoral artery and advanced to the ascending aorta. In some patients, however, the femoral arteries are not suitable for catheter manipulation due to severe atherosclerosis. Alternatively, the catheter can be inserted through right antecubital area 34 or left antecubital area 36. Elongate member 1 of the catheter is shown inserted through

antecubital area 34 and advanced through the right brachial artery and brachiocephalic trunk to enter the ascending aorta. After final placement of the catheter in the ascending aorta, expandable filter 10 is expanded to entrap emboli and balloon occluder 5 is inflated to provide circulatory isolation of the heart and coronary blood vessels from the peripheral vascular system.

It will be understood that the devices disclosed herein are particular well suited to application for valve repair surgeries because these surgeries are recognized to generate embolic material upstream of the site of aortic blockage. According to McBride et al., *Glenn's Thoracic and Cardiovascular Surgery*, 6th Ed., Vol. II (1986), incorporated herein by reference, median sternotomy is often the incision used for replacing the aortic valve or any combination of valves in which the aortic valve is included. After venous cannulation of the right atrium, inferior vena cava, or superior vena cava, arterial cannulation of the aorta is established for cardiopulmonary bypass using the percutaneous filtration catheter disclosed herein. The catheter is positioned in the ascending aorta via femoral artery or brachial artery access. The balloon occluder, or other impermeable dam, is deployed to isolate the heart from peripheral circulation. The filter is deployed upstream of the occluder in order to capture calcified plaque from the aortic or mitral valve. Oxygenated blood from a bypass machine is infused through the catheter downstream of the occluder. Cardioplegia solution is administered to the aortic root while the aortic valve is manually closed by external pressure on the root of the aorta or directly into the coronary ostia.

In aortic valve repair, the aorta is opened through a transverse incision approximately 1 to 1.5 centimeters above the right coronary artery. The standard approach to mitral valve repair is often through an incision parallel to the intra-atrial groove into the left atrium. After the heavily calcific or fibrotic valve is resected sufficiently to permit visualization of the left ventricular chamber, a sponge is often placed in this cavity to enmesh any calcium that may fragment from the annulus during decalcification. A culture stick placed in the left coronary orifice prevents embolization of calcium into this vessel, and the retractor providing exposure of the valve usually blocks the right coronary orifice. A prosthetic valve is sutured into the valvular annulus after the diseased native valve is removed. The aorta is then closed with two layers of sutures. Aortic occlusion and filtration is removed, and the patient is taken off cardiopulmonary bypass.

Although the foregoing invention has, for purposes of clarity of understanding, been described in some detail by way of illustration and example, it will be obvious that certain changes and modifications may be practiced which will still fall within the scope of the appended claim.

Claims

1. A percutaneous filtration catheter, comprising:
an elongate member having a proximal end and a distal end;
a balloon occluder mounted on the distal end of the elongate member, the
5 balloon defining a chamber which communicates with a lumen carried by the elongate
member; and
an expandable filter mounted on the elongate member distal the balloon
occluder, the expandable filter operable independently of the balloon occluder.
2. The catheter of claim 1, wherein the balloon occluder comprises an
10 elastomeric balloon.
3. The catheter of claim 1, further comprises a second lumen for infusion of
fluid.
4. The catheter of claim 3, wherein the second lumen is adapted to receive a
pressure monitor.
- 15 5. The catheter of claim 1, wherein the expandable filter is operable from the
proximal end of the elongate member.
6. The catheter of claim 1, wherein the expandable filter further comprises an
expansion frame.
7. The catheter of claim 6, wherein the expansion frame comprises an
20 umbrella frame.
8. The catheter of claim 6, wherein the expansion frame comprises an
inflation seal.
9. The catheter of claim 1, wherein the expandable filter is operable by
manipulating at least one pull string.

10. The catheter of claim 1, wherein the expandable filter has a proximal edge bonded circumferentially and continuously to the elongate member, and a distal edge which expands radially on activation.

11. A method of percutaneous filtration for heart surgery, comprising the steps
5 of:

providing an elongate member having a proximal end, a distal end, a balloon occluder mounted on the distal end of the elongate member, and an expandable filter mounted on the elongate member distal the balloon occluder;

10 inserting the elongate member through a percutaneous incision, and
advancing the distal end of the catheter into the ascending aorta;
expanding the filter;
inflating the balloon occluder; and
performing surgery on the heart.

12. The method of claim 11, wherein the percutaneous incision is in a patient's
15 femoral artery.

13. The method of claim 11, wherein the percutaneous incision is in a patient's intercostal space.

14. The method of claim 11, wherein the filter is operable from the proximal end of the elongate member.

20 15. The method of claim 11, wherein the surgery is heart valve repair.

16. The method of claim 11, wherein the surgery is septal defect repair.

17. The method of claim 11, wherein the expandable filter further comprises an expansion frame.

25 18. The method of claim 17, wherein the expansion frame comprises an umbrella frame.

19. The method of claim 17, wherein the expansion frame comprises an inflation seal.

20. The method of claim 11, wherein the expandable filter is operable by manipulating at least one pull string.

21. The method of claim 11, wherein the expandable filter has a proximal edge bonded circumferentially and continuously to the elongate member, and a distal edge
5 which expands radially on activation.

22. The method of claim 11, wherein the step of inflating the balloon occluder is performed before the step of expanding the filter.

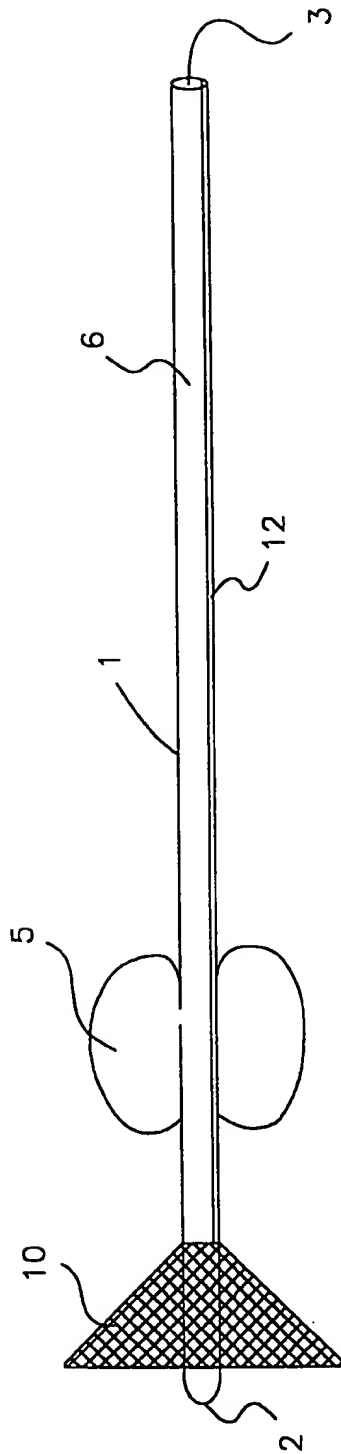


FIG. 1

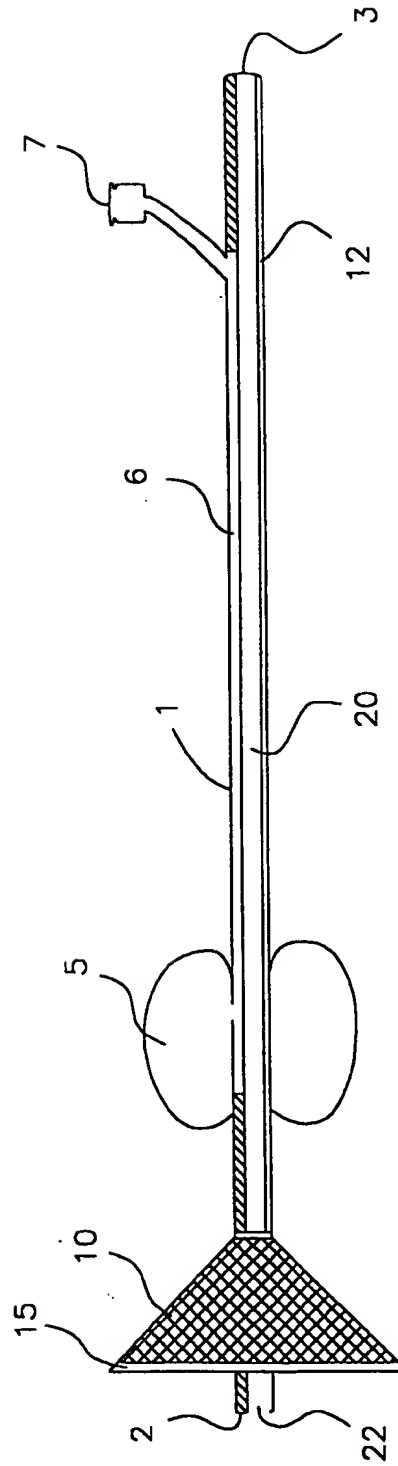
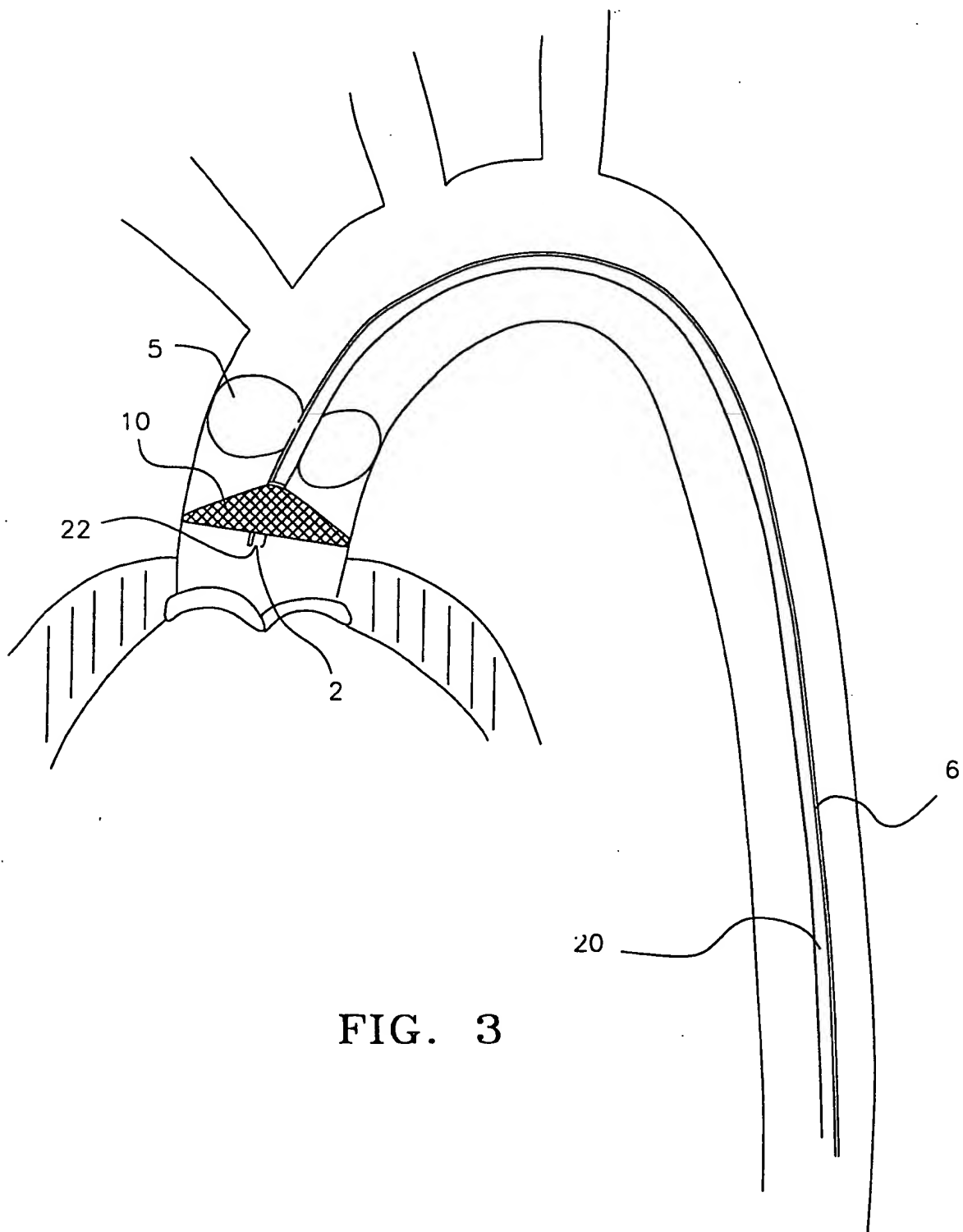


FIG. 2

2/3



3/3

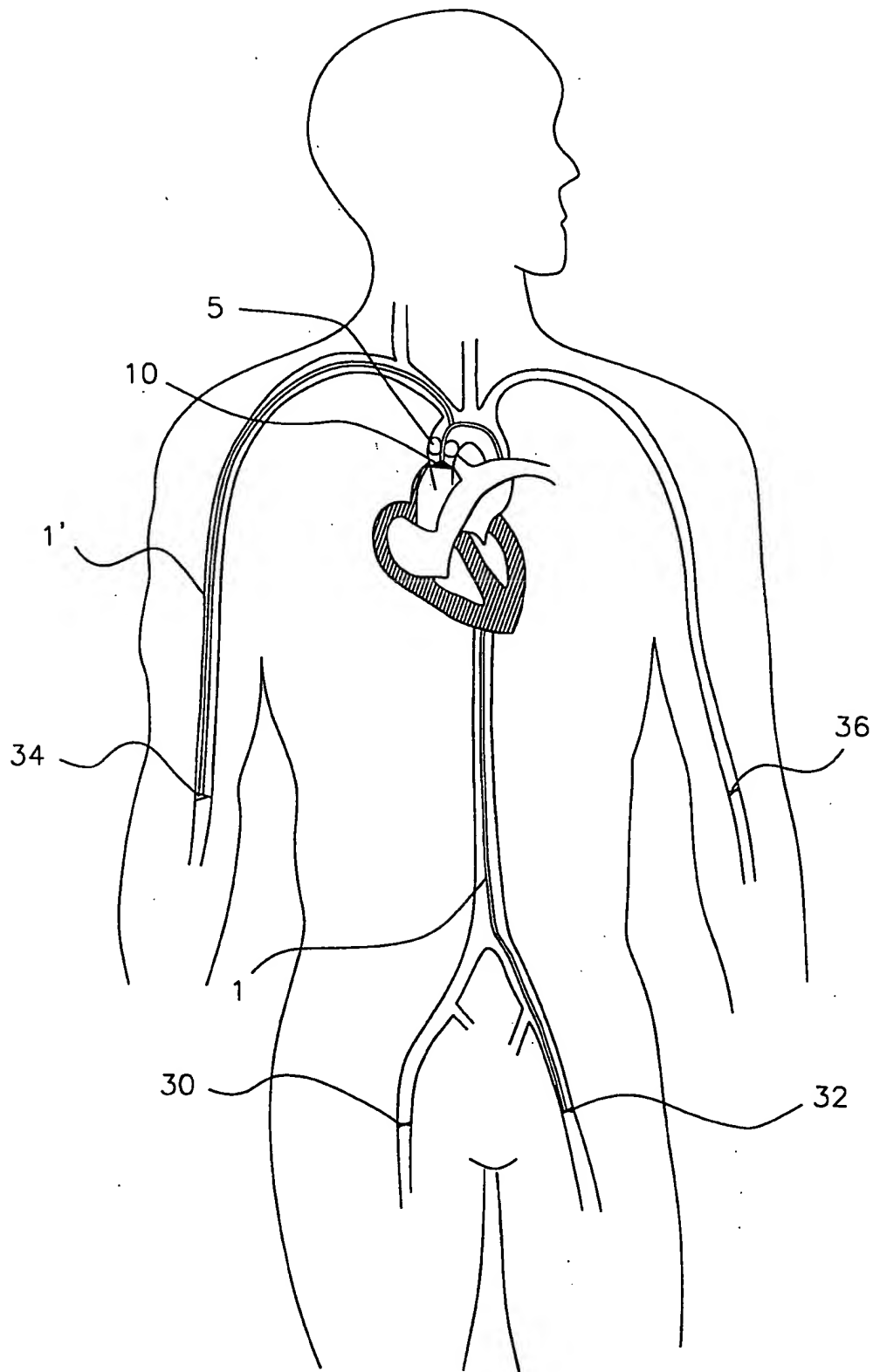


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/23528

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 29/00

US CI : 606/194, 198, 200

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/194, 198, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,769,871 A (MERS KELLY et al.) 23 June 1998, col. 1 lines 54-67, and col. 2 lines 1-37.	1-10
A	US 5,769,816 A (BARBUT et la.) 23 June 1998, col. 3 lines 34-43.	1-10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

08 DECEMBER 1999

Date of mailing of the international search report

13 MAR 2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/23528**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 11-22
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 11-22 are drawn to a surgical procedure, which is non-statutory subject matter.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.